HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

3013 '02 JUL 10 A9:34

Ferndale Laboratories, Inc.
Attention: Deborah L. Theres
780 West Eight Mile Road
Ferndale, MI 48220

JUL - 3 2002

Docket No. 01P-0291/CP1

Dear Ms. Theres:

This is in response to your petition filed on July 2, 2001, and your amendment dated November 7, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Lidocaine Cream, 5%. The listed drug product to which you refer in your petition is Xylocaine® (Lidocaine) Ointment 5% approved under NDA 08-048 held by AstraZeneca, LP.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Section 505(j)(2)(C)(i) of the Act such a petition will be approved unless the Agency finds that investigations must be conducted to show the safety and effectiveness of the proposed drug product's dosage form that differs from that of the listed drug product.

Your request involves a change in dosage form from that of the listed drug product (i.e., from an ointment to a cream). The change that you request is the type of change that is authorized under Section 505(j)(2)(C) of the Act.

This petition was evaluated with respect to the Regulations Requiring Manufactures to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published Wednesday, December 2, 1998, in the Federal Register (Pediatric Rule)(63 FR 66632). The agency has determined that your proposed change in dosage form is subject to the Pediatric Rule and has concluded that investigations are necessary to demonstrate the safety and effectiveness in the pediatric population.

In addition, the Agency has determined that your proposed change in dosage form raises questions of safety and effectiveness, and has concluded that clinical trials are required for this specific drug product. Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug product. To the extent that changes in formulation affect the absorption of lidocaine into the

01P-0291 PDN1

systemic circulation, you will need to conduct clinical studies to demonstrate that efficacy and safety of the proposed product are not compromised by the new formulation. In addition, you will need to document that the amount of lidocaine absorbed into the systemic circulation, if any is safe. These concerns apply to children as well as adults. You must also demonstrate through clinical studies that the recommended pediatric doses are safe and effective for the proposed dosage form in the pediatric population. Please submit an IND to the Division of Anesthetic, Critical Care, and Addiction Drug Products, HFD-170, (301)-827-7410.

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research